

REMARKS

Claims 1-22 are pending in the instant application. Claims 17-22 are withdrawn from further consideration pursuant to the provisions of 37 CFR §1.142(b), as being drawn to nonelected inventions. Applicants have hereinabove cancelled claims 13-16 without prejudice or disclaimer to their right to pursue the subject matter of these claims in a future application. In addition, applicants have hereinabove amended claim 1 and added new claims 23 and 24. Support for the amendments to the claims may be found, *inter alia*, in the subject specification as follows: claim 1: page 20, lines 5-16; claim 23: page 18, line 10; and claim 24: page 18, lines 25-30. The remaining changes to the claims merely introduce minor grammatical and format changes. In addition, applicants have hereinabove amended the specification to add a Sequence Listing and sequence identifiers as required under 37 CFR §1.1821. This Amendment does not involve any issue of new matter. Therefore, entry of this Amendment is respectfully requested such that claims 1-12, 23 and 24 will be pending and under examination.

Election/Restriction

The Examiner required restriction under 35 U.S.C. §§ 121 and 372 to one of the following inventions:

Group I, claims 1-16, drawn to a method for determining whether an analyte has a mixed androgen receptor agonist, antagonist or partial activity; and

Group II, claims 17-22, drawn to a method for determining the ratio of agonist to antagonist activity of an analyte.

The Examiner stated that during a January 6, 2008 telephone conversation with David Reilly, Esq. of the undersigned office a provisional election was made without traverse to prosecute the invention of Group I. The Examiner requires affirmation of this election in response to the subject office action.

In response, applicant confirms the election of Group I, claims 1-16 and new claims 23 and 24, drawn to a method for determining whether an analyte has a mixed androgen receptor

agonist, antagonist or partial activity, without traverse, such that these claims are now under examination.

Claim Objection

The Examiner objected to claims 1 and 6 for the following alleged informalities. The Examiner stated that with respect to claim 1, step (a), applicant recites "full length human AR" and "AR ligand binding domain polypeptide." The Examiner conceded that both are known in the literature and suggested that applicant recite the SEQ ID NOS for clarity.

In response, applicant respectfully traverses. Nevertheless, applicant without conceding the correctness of the Examiner's objection and to expedite prosecution of the subject application, has hereinabove amended claim 1 such that it now recites the SEQ ID NO for full length human AR. As the Examiner conceded such polypeptide was known in the art as evidenced by the Genbank entry attached hereto as **Exhibit 3** for the cell line MDA-MB-453, which was published in 1999, i.e. prior to the filing of the subject application, and which contains the nucleic acid (SEQ ID NO:1) and amino acid (SEQ ID NO:2) sequences for full length human AR, which are endogenously present in the cell line MDA-MB-453.

In addition, applicant has hereinabove added new claim 24 which recites the SEQ ID NO: 3 for rhesus monkey AR polypeptide, which was also known in the art as evidenced by US Patent No. 7,060,463, a copy is attached hereto as **Exhibit 4**, which is a 35 U.S.C. §371 national stage application of WO02/090529, published November 14, 2002, i.e. prior to the filing of the subject application, and also referenced by applicant at page 18, lines 25-29 of the subject application.

Applicants also enclose a computer diskette containing the Sequence Listing in computer readable form. In addition, applicants attach hereto as **Exhibit 1** a paper copy of the computer readable form of the Sequence Listing. Applicant also attaches hereto as **Exhibit 2** a Statement In Compliance with 37 C.F.R. §1.821(f) certifying that the computer readable form contains the same information as the paper copy of the Sequence Listing attached as Exhibit 1. The Sequence Listing does not contain any new matter.

In light of the above remarks, applicants maintain that claim 1, and the claims which depend therefrom, satisfy the Examiner's objection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of objection.

Deposit

The Examiner stated that with respect to claims 4 and 14 applicant is required to make a statement for the deposited cell lines recited therein.

In response, applicant respectfully traverses. Nevertheless, applicant without conceding the correctness of the Examiner's requirement and to expedite prosecution of the subject application, has hereinabove cancelled claims 4 and 14 without prejudice or disclaimer. Therefore, applicant respectfully notes that the requirement is now moot.

Claim Rejection Under 35 U.S.C. §112, first paragraph

The Examiner rejected claims 1-16 under 35 U.S.C. §112, first paragraph, as allegedly failing to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The Examiner stated that the specification does not reasonably provide enablement for simply "substantially the same" or "less than" a second IC50 as recited in step (d) of claim 1 as distinguishing full agonist, full antagonist or mixed agonist. However, the Examiner conceded that the specification is enabling for a significantly five-fold threshold in IC50.

In response, applicants respectfully traverse. Nevertheless, applicants, without conceding the correctness of the Examiner's position and to expedite prosecution of the subject application, have herein amended claim 1 to address the Examiner's rejection. Claim 1, as amended, recites "a five-fold " difference in IC50 which is described in the subject specification.

In view of the above remarks, applicants maintain that claim 1, and claims 2-12, 23 and 24 which depend therefrom, satisfy the enablement requirement of 35 U.S.C. §112, first paragraph. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Summary

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and withdraw the various grounds of objection and rejection, and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone her at the number provided below.

No fee, other than the fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the large entity amount of such fee to Deposit Account No. 13-2755 referencing attorney docket number 21506YP.

Respectfully submitted,

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EXHIBIT 1